

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DEAN LANGFORD and)	
NANCY LANGFORD,)	
husband and wife,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 03-12245-RCL
)	
ZIMMER, INC. and)	
ZIMMER HOLDINGS, INC.,)	
)	
Defendants.)	

**RESPONSE IN OPPOSITION TO PLAINTIFFS'
MOTION TO AMEND THEIR FIRST AMENDED COMPLAINT**

Zimmer, Inc. and Zimmer Holdings, Inc. ("Zimmer"), by their attorneys, respectfully oppose Plaintiffs' motion to amend their complaint because certain of the amendments would be futile and all of the amendments are unduly delayed. In support of its opposition to Plaintiffs' motion, Zimmer states as follows:

I. INTRODUCTION

On November 13, 2003, Dean and Nancy Langford filed a complaint against Zimmer alleging claims of negligence, strict liability (failure to warn), strict liability (defective design, manufacture and testing), breach of express and implied warranties, and loss of consortium. Zimmer filed its answer subject to a motion to strike on February 27, 2004. This Court granted Zimmer's motion to strike portions of the complaint in part on May 4, 2004, striking a paragraph outlining Zimmer's alleged profits. Plaintiffs filed their First Amended Complaint on May 26,

2004, and in doing so eliminated the offending paragraph. Zimmer timely filed its amended answer. Plaintiffs now seek leave to amend their complaint a second time.

In their Motion to Amend, Plaintiffs claim to seek only three changes: (1) added allegations that other Zimmer products are defective; (2) the addition of a claim of unfair or deceptive practices; and (3) the correction of some typographical errors. [Motion at p. 1.] Plaintiffs portray their amendments as inconsequential but a review of the draft second amended complaint reveals that Plaintiffs seek to add the following substantive allegations to their Complaint:

- (1) allegations that Zimmer failed to warn Mr. Langford's doctors [Draft Second Amended Complaint, ¶ 31];
- (2) allegations regarding other Zimmer products, including a femoral head, an acetabular component, and acetabular liners [*Id.* at ¶¶ 34—36, 40, 41, 42 and subparts (a),(b), (d), and (e), 43, 47—51, 54, 55, 57, and 60];
- (3) allegations regarding the Zimmer hip product or products received during Plaintiff's revision surgery [*Id.* at ¶ 37];
- (4) additional claimed injury because Plaintiff "and his doctors were not adequately informed about the full extent of the medical problems which can be caused by premature loosening of the Centralign hip prosthesis" [*Id.* at ¶38];
- (5) "other" forms of lost compensation in addition to lost wages [*Id.*];
- (6) additional expenses Plaintiffs "have incurred and will in the future incur" for "activities [Plaintiff] would have otherwise done himself" [*Id.*];

- (7) additional alleged grounds for a claim of negligence, i.e. Zimmer's failure "to adequately convey to physicians and patients...a number of important facts about [other Zimmer hip products]" [*Id.* at ¶ 42(g)];
- (8) a claim of unfair or deceptive acts or practices pursuant to Chapter 93A [*Id.* at ¶¶62—67];
- (9) a claim for attorneys fees and costs pursuant to Chapter 93A [*Id.* at 70(b)]; and
- (10) a claim for double or treble damages pursuant to Chapter 93A [*Id.* at 70(c)].

Plaintiffs' only claimed basis for filing their Motion is that "they have identified additional claims against the defendants (Zimmer) which relate to injuries which defendants' products have caused plaintiffs." [Motion at p. 2.] Plaintiffs do not claim to have discovered any new information that was unavailable to them at the time the initial complaint was filed. Plaintiffs have no legitimate basis for not having made these allegations previously.

II. ARGUMENT

Rule 15 of the Federal Rules of Civil Procedure permits a party to amend a pleading once as a matter of course at any time before a responsive pleading is served. Rule 15 states that leave to amend after the responsive pleading is served "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Leave to amend, however, is not automatic, and may be denied for good cause, "such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the amendment, futility of amendment, etc." *Foman v. Davis*, 371 U.S. 178, 182 (1962). The decision to grant or deny a motion to amend pleadings is "left to the broad discretion of the district court." *Coyne v. Somerville*, 972 F.2d 440, 446 (1st Cir. 1992).

Plaintiffs' Motion to Amend should be denied for two independent reasons: (1) the Chapter 93A amendments Plaintiffs seek would be futile and (2) all of the amendments are unduly delayed.

A. Plaintiffs' Proposed Chapter 93A Amendments Would Be Futile

Where a plaintiff's proposed amendment would fail to state a claim upon which relief could be granted, the amendment is "futile" and leave to amend should be denied. *See Glassman v. Computervision Corp.*, 90 F.3d 617, 623 (1st Cir. 1996). Courts within this district have consistently held that claims against medical device manufacturers under Mass. Stat. Gen. Ch. 93A ("Chapter 93A") are futile because they are preempted by the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Shumaker v. C.R. Bard, Inc.*, Civ. A. No. 94-11321-MLW, 1996 WL 33828, at *3 (D. Mass. Jan. 3, 1996); *Fisher v. C.R. Bard, Inc.*, Civ. A. No. 94-11324-MLW, 1996 WL 33818 at *3 (D. Mass. Jan. 3, 1996).

The preemption provision of the MDA provides in pertinent part that:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
 (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
 (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a) ¹. One of the federal Food and Drug Administration's ("FDA's") regulations interpreting this statute provides that:

Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial

¹ Part (b) of the statute creates a process by which a state may seek a specific exemption to the preemption rule. 21 U.S.C.A. § 360k(b). The State of Massachusetts has not received such an exemption with respect to claims of unfair trade practices with regard to a medical device. 21 C.F.R. § 808.71 (2004).

Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d)(1) (2004). However, federal courts interpreting the MDA and this regulation in conjunction with Chapter 93A have uniformly ruled that Chapter 93A is preempted by the MDA because the regulation is inconsistent with Congressional intent. *Shumaker*, 1996 WL 33828, at *3; *Fisher*, 1996 WL 33818, at *3; *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37, 49 (D. Mass. 1994). Because the *Talbott* court found that § 808.1(d)(1) was “contrary to clear Congressional intent,” the court was compelled to “follow the commands of Congress rather than the FDA’s erroneous interpretations of them” and accordingly the court held that all of the plaintiff’s common law and statutory claims, including the Chapter 93A claim, were preempted and therefore futile. 865 F. Supp. at 49.² Because state statutory claims against medical device manufacturers are preempted, Plaintiffs have not alleged a colorable claim under Chapter 93A and their motion for leave to amend to add the Chapter 93A claim must be denied as futile.

B. All of Plaintiffs’ Proposed Amendments Are Unduly Delayed

Under clear federal precedent, amendments cannot be permitted if they are unduly delayed. *Foman*, 371 U.S. at 182. The delay is undue and a motion to amend is properly denied when “[t]he facts upon which the proposed [amendment] rested were known to [the moving party] all along...[and the moving party] never proffered a satisfactory explanation for its delay.” *Quaker State Oil Refining Corp. v. Garrity Oil Co.*, 884 F.2d 1510, 1517-18 (1st Cir. 1989). *See*

² Subsequent to this district court’s decisions in *Shumaker*, *Fisher*, and *Talbott*, the United States Supreme Court issued its opinion in *Medtronic, Inc. v. Lohr* 518 U.S. 470 (1996). In *Medtronic*, the Court ruled that the MDA did not preempt certain state common law claims. *Id.* at 501. *Medtronic*’s holding does not affect the force and effect of *Shumaker*, *Fisher*, and *Talbott*. Although Zimmer could locate no post-*Medtronic* case in the Massachusetts district court or First Circuit analyzing any potential change in Chapter 93A preemption in light of *Medtronic*, a district court opinion does acknowledge that *Medtronic*’s holding is limited to state common law claims. *Comeau v. Heller*, 945 F. Supp. 7, 12 (D. Mass. 1996). Accordingly, *Shumaker*, *Fisher*, and *Talbott* are good law with respect to Chapter 93A’s preemption status.

also Gianfriddo v. Western Union Telegraph Co., Civ. A. No. 84-3273-MA, 1985 WL 48174 (D. Mass. 1985)(plaintiff's motion to amend denied because plaintiff could have asserted claim previously and offered no reason for delay). The prohibition against undue delay applies to bar amendments even without a showing of prejudice to the opposing party. *Deghand v. Wal-Mart Stores, Inc.*, 904 F. Supp. 1218, 1221 (D. Kan. 1995). Here, the Plaintiffs' proposed amendments are not based on any newly learned facts. Indeed, in Plaintiffs' own words, their proposed amended complaint "in large part addresses facts previously alleged." [Motion at p. 3.] Further, Plaintiffs have given no explanation for their delay. In light of these facts, Plaintiffs' motion is properly denied in its entirety.

III. CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Amend Their First Amended Complaint should be denied.

Respectfully submitted,

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DAY, BERRY & HOWARD, LLP

By: /s/ Edgar B. Hatrick
 Edgar B. Hatrick (#647166)
 Day, Berry & Howard LLP
 260 Franklin Street
 Boston, MA 02110
 Telephone: (617) 345-4600
 Facsimile: (617) 345-4745

Matthew S. Elvin (pro hac vice)
 Dahm & Elvin LLP
 9604 Coldwater Road, Suite 201
 Fort Wayne, IN 46825
 Telephone: (260) 497-6000
 Facsimile: (260) 497-6019

ATTORNEYS FOR DEFENDANTS ZIMMER, INC. AND
 ZIMMER HOLDINGS, INC.

CERTIFICATE OF SERVICE

The undersigned certifies that on the 26th day of July, 2004, a copy of the foregoing Defendant Zimmer's Response in Opposition to Plaintiffs' Motion to Amend Their First Amended Complaint was served on the following counsel of record by first-class mail, postage prepaid:

Wm. Gerald McElroy, Jr.
Paul T. Sullivan
Zelle, Hofmann, Voelbel, Mason & Gette LLP
950 Winter Street, Suite 1300
Waltham, MA 02451

Fred H. Pritzker
Peter H. Berge
Elliot L. Olsen
Pritzker Ruohonen & Associates, P.A.
33 South Sixth Street, Suite 4520
Minneapolis, MN 55402-3792

James S. Reece
Chad A. Snyder
Elizabeth A. Maki
Zelle, Hofmann, Voelbel, Mason & Gette LLP
500 South Washington Avenue - Suite 4000
Minneapolis, MN 55415

/s/ Edgar B. Hatrick

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